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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,797	11/28/2000	Jon S. Thorson	2653/40	7811

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EXAMINER

PAPPU, SITA S

ART UNIT	PAPER NUMBER
1636	9

DATE MAILED: 02/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/724,797	THORSON, JON S.
	Examiner	Art Unit
	Sita Pappu	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-9, 57, 58, 88-101, 142-146, 148 and 149 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-9, 57, 58, 88-101, 142-146, 148 and 149 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

## DETAILED ACTION

Preliminary amendment filed 07/03/2001 has been entered. Claims 10-56, 59-87, 102-141 and 147 are cancelled. Claims 9, 57, 58 and 101 are amended. Currently, claims 1-9, 57, 58, 88-101, 142-146, 148, 149 are pending in the instant application.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-48: Claims 1-9, 57, 58, 88-95, 96-99, 145, 146, 148, drawn to an isolated nucleic acids of SeqIDNos: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 79, 81, 83, 85, 87, 89, 91, 93 or 94, respectively for Groups 1-48, encoding the genes namely, calA, calB, calC, calD, calE, calF, calG, calH, calI, calJ, calK, calL, calM, calN, calO, calP, calQ, calR, calS, calT, calU, calV, calW, calX, 6MSAS, ActI, ActII, ActIII, orf1, orf2, orf3, orf4, orf5, orf6, orf7, orf8, orfI, orfII, orfIII, orfIV, orfV, orfVI, orfVII, orfVIII, orfIX, orfX, orfXI, an IS-element gene respectively for Groups 1-48, and to a nucleic acid sequence encoding the protein of SeqIDNos: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92

or 95, respectively for Groups 1-47, vector and host cell, classified in class 435, subclass 320.1.

Group 49: Claim 100, drawn to a method of purifying calicheamicin using affinity chromatography, classified in class 435, subclass 803.

Groups 50-96: Claims 101, 149, drawn to a polypeptide of SeqIDNos: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92 or 95, respectively for Groups 50-96, classified in class 530, subclass 300.

Group 97: Claim 142, drawn to a method of conferring calicheamicin resistance on a subject by ex vivo methods, classified in class 424, subclass 93.21.

Group 98: Claim 143, 144, drawn to a compound, classified in class 260.

Claims 2, 8 and 97 embrace the Inventions of Groups 1-48 and are directed to the genes encoding calA, calB, calC, calD, calE, calF, calG, calH, calI, calJ, calK, calL, calM, calN, calO, calP, calQ, calR, calS, calT, calU, calV, calW, calX, 6MSAS, ActI, ActII, ActIII, orf1, orf2, orf3, orf4, orf5, orf6, orf7, orf8, orfI, orfII, orfIII, orfIV, orfV, orfVI, orfVII, orfVIII, orfIX, orfX, orfXI, an IS-element gene. These genes comprise independent Inventions and therefore, Applicant is required to elect one of the Groups

1-48 for examination on the merits. Should one of these Groups be elected, claims 2, 8, and 97 will be examined only to the extent they encompass the elected subject matter.

Claims 9 and 148 embrace the Inventions of Groups 1-48 and are drawn to SeqID Nos: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 79, 81, 83, 85, 87, 89, 91, 93 or 94. These sequences comprise independent Inventions and therefore, Applicant is required to elect one of the sequences that correspond to the elected gene of claims 2, 8 and 97, for examination on the merits. Should one of these Groups 1-48 be elected, claims 9 and 148 will be examined only to the extent they encompass the elected subject matter.

Claim 58 embraces the Inventions of Groups 1-48 and is drawn to a membrane transporter, an O-methyl transferase, a glycosyltransferase, a N,N-dimethyltransferase, a dipeptide transporter, an L-cysteine/cystine C-S-lyase, an oligopeptide transporter protein, a regulatory protein, a desaturase, a transcriptional regulator, an oxygenase, a halogenase, a  $\beta$ -keto-acyl synthase III, a cytochrome P450, a TDP-4-keto-6-deoxy-L-hexose 2,3-dehydrogenase, an orsellinic acid synthase, a polyketide cyclase, a polyketide synthase, an integrase, a chromosome partitioning protein, a hydroxylase, an aminotransferase, a glu-ammonia-ligase and adenylyltransferase, a methyltransferase, an integral membrane protein, a membrane protein, an immunity resistance protein, or an insertional element. These proteins comprise independent Inventions and therefore, Applicant is required to elect one of the proteins that correspond to the elected gene and the nucleic acid sequence of Groups 1-48, for examination on the merits.

Should one of these Groups 1-48 be elected, claim 58 will be examined only to the extent it encompasses the elected subject matter.

Claims 101 and 149 embrace the Inventions of Groups 50-96 and are drawn to SeqIDNos: SeqID Nos 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92 or 95. These polypeptide sequences comprise independent Inventions and therefore, Applicant is required to elect one of the sequences for examination on the merits. Should one of these Groups 50-96 be elected, claims 101 and 149 will be examined only to the extent they encompass the elected subject matter.

Claims 145 and 146 embrace the Inventions of Groups 1-48 and are drawn to nucleic acids encoding the proteins of SeqIDNos: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92 or 95. These nucleic acids encoding the polypeptide sequences comprise independent Inventions and therefore, Applicant is required to elect one of the sequences that correspond to the gene and/or nucleic acid sequences elected from Groups 1-48, for examination on the merits. Should one of these Groups 1-48 be elected, claims 145 and 146 will be examined only to the extent they encompass the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Groups 1-48 are directed to an isolated nucleic acid molecule, vector and host cell, while group 49 is directed to affinity chromatographic methods. These two groups

are independent because these two groups have different modes of operation, function, effects and starting materials. Further, the methods of using nucleic acids are different from those of affinity chromatography.

Groups 50-96 are directed to a polypeptide. Peptides and nucleic acids are substantially different in terms of structural, chemical, physical and biological properties, are made using substantially different techniques and can be used for substantially different purposes. It is particularly noted that the nucleic acid is not required for the production of the peptide as peptides can be synthesized or purified from cells. Thus, Groups 1-48 are independent from Groups 50-96.

Groups 97 and 98 are directed to ex vivo methods of use and to a compound respectively, and are materially and procedurally distinct from those of other Groups.

Group 49 is distinct from Groups 50-98, because it involves biochemical methods that are distinct from the methods of Groups 50-98. Further, the polypeptide of Groups 50-96 can be synthesized by various methods or purified from cells.

Groups 50-96 are directed to a polypeptide and Group 97 is directed to ex vivo methods. The polypeptide of Groups 50-96 is not required for the methods of Group 97 and vice versa. Thus, Groups 50-96 are independent from Group 97.

Groups 50-96 are directed to a polypeptide while Group 98 is directed to a compound and, Groups 50-96 are thus, independent of Group 98.

Groups 97 and 98 are independent of each other. The ex vivo methods of Group 97 are not required for Group 98 and the compound of Group 98 is not required for the methods of Group 97.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and search, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that a reply to this requirement must include an identification of the Invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. If claims are added after the election, applicant must indicate which are readable upon the elected Invention. MPEP § 809.02(a).

Should applicant traverse on the ground that the Inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the Inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746 7442 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-2982.

*Anne-Marie Baker*

ANNE-MARIE BAKER  
PATENT EXAMINER

S. Pappu  
February 8, 2002